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Dated: December 16, 2005

Signature: \_\_\_\_\_

(Lenay Rogus)

Patent

Docket No. 532552000102

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Paul TARDI et al.

Serial No.: 10/553,373

Filing Date (Int'l): April 16, 2004

For: COMPOSITIONS FOR DELIVERY OF  
DRUG COMBINATIONS

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

### INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98

MS PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.

The document numbers 2, 3, and 37 listed on the attached Form PTO/SB/08a/b were cited in an International Search Report mailed on February 9, 2005, directed to a counterpart international or foreign application and have not been previously cited.

sd-288517

This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
  - ☐ A fee is required. A check in the amount of \_\_ is enclosed.
  - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of \_\_ is enclosed.
  - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has

been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing 532552000102.

Dated: December 14, 2005

Respectfully submitted,

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/553,373
				Filing Date	(Int'l) April 16, 2004
				First Named Inventor	Paul TARDI
				Art Unit	Not Yet Assigned
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	532552000102

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US-5,000,958	03-19-1991	Fountain et al.	
	2.	US-5,055,291	10-08-1991	Lam et al.	
	3.	US-5,547,940	08-20-1996	Nice et al.	
	4.	US-5,736,155	04/1998	Bally et al.	
	5.	US-6,214,821	04-10-2001	Daoud	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	6.	WO-00/51641	09/2000			
	7.	WO-01/15733	03/2001			

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	8.	BARRIERE et al., "Bacterial Resistance to β-Lactams, and Its Prevention with Combination Antimicrobial Therapy" Pharmacotherapy 12:397-402 (1992)		
	9.	BONNER and KOZELSKY, "The Significance of the Sequence of Administration of Topotecan and Etoposide" Cancer Chemother. Pharmacol. 39:109-112 (1990)		
	10.	CHEN et al., "Combination of All-Trans Retinoic Acid with Butyric Acid and Its Prodrugs Markedly Enhancing Differentiation of Human Acute Promyelocytic Leukemia NB <sub>4</sub> Cells" Chin. Med. Engl. 112:352-355 (1999)		
	11.	CUNNINGHAM, "Current Status of Colorectal Cancer: CPT-11 (Irinotecan), a Therapeutic Innovation" Eur. J. Cancer 32A(Suppl. 3):S1-S8 (1996)		
	12.	DAOUD et al., "Synergistic Cytotoxic Actions of Cisplatin and Liposomal Valinomycin on Human Ovarian Carcinoma Cells" Cancer Chemother. Pharmacol. 28:370-376 (1991)		
	13.	ENGBLOM et al., "Additive and Supra-Additive Cytotoxicity of Cisplatin-Taxane Combinations in Ovarian Carcinoma Cell Lines" Br. J. Cancer 79:286-292 (1999)		
	14.	ENZINGER and ILSON, "Irinotecan in Esophageal Cancer" Oncology 14(12, Suppl. 14):26-30 (2000)		
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	16.	FREI et al., "The Relationship between High-Dose Treatment and Combination		

Examiner Signature		Date Considered	
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sd- 288487

Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/553,373	
			Filing Date	(Int'l) April 16, 2004	
			First Named Inventor	Paul TARDI	
			Art Unit	Not Yet Assigned	
			Examiner Name	Not Yet Assigned	
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		Chemotherapy: The Concept of Summation Dose Intensity" Clin. Cancer Res. 4:2027-2037 (1998)	
17.		GUICHARD et al., "Cellular Interactions of 5-Fluorouracil and the Camptothecin Analogue CPT-11 (Irinotecan) in a Human Colorectal Carcinoma Cell Line" Biochemical Pharmacology 55:667-676 (1998)	
18.		HOFS et al., "Concentration and Sequence Dependent Synergism of Ethyldeshydroxy-Sparsomycin in Combination with Antitumor Agents" Anticancer Drugs 5:35-42 (1994)	
19.		International Search Report for PCT/US04/11812, mailed on February 9, 2005, 2 pages	
20.		KANO et al., "Effects of Carboplatin in Combination with Other Anticancer Agents on Human Leukemia Cell Lines" Leukemia Res. 17(2):113-119 (1993)	
21.		KANZAWA et al., "Evaluation of Synergism by a Novel Three-Dimensional Model for the Combined Action of Cisplatin and Etoposide on the Growth of a Human Small-Cell Lung-Cancer Cell Line, SBC-3" Int. J. Cancer 71(3):311-319 (1997)	
22.		KOBAYASHI et al., "HTCA (Human Tumor Clonogenic Assay). Probability About the Combination Use of Cisplatin and Carboplatin" Nippon Chiryo Gakkai Shi 25:2684-2692 (1990)	
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25.		MANS et al., "Sequence-Dependent Growth Inhibition and DNA Damage Formation by the Irinotecan-5-Fluorouracil Combinations in Human Colon Carcinoma Cell Lines" Eur. J. Cancer 35(13):1851-1861 (1999)	
26.		MASSIN et al., "Acute Arrhythmogenicity of First-Dose Chemotherapeutic Agents in Children" Med. Pediatr. Oncol. 39:93-98 (2002)	
27.		SAXON et al., "Liposomal Anticancer Drugs as Agents to be Used in Combination with Other Anticancer Agents: Studies on a Liposomal Formulation with Two Encapsulated Drugs" J. Liposome Res. 9:507-522 (1999)	
28.		SCHIFFELERS et al., "In Vivo Synergistic Interaction of Liposome-Coencapsulated Gentamicin and Ceftazidime" J. Pharmacol. Exp. Therapeutic 298:369-375 (2001)	
29.		SCHIMPF, "Gram-Negative Bacteremia" Support Care Cancer 1:5-18 (1993)	
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33.		SONG et al., "Rapid Report. A Novel Polymeric Conjugate Carrying Two Different Anticancer Drugs" Polym. Int. 48:627-629 (1999)	
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Sheet	3	of	3	Attorney Docket Number	532552000102

	38.	VAAGE et al., Int. J. Cancer (1993) 54:959-964	
	39.	VOGLER, W., "High-Dose Carboplatin in the Treatment of Hematologic Malignancies" Oncology 50(Suppl. 2):42-46 (1993)	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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